(6)

Ms. Jane Axelad, Associate Director for Policy
Center for Drug Evaluation and Research
Food and Drug Administration
Woodmont Building, Room 6027
Rockville, Maryland 20852

Dear Ms. Axelrad,

As you may recall, I presented some material pertaining to the use of DMPS (dimercapto propane sulfonate) to the Pharmacy Compounding Advisory Committee on July 13, 2000. After my presentation, there was some indication that no MedWatch reports had been received regarding this drug.

I thought that I had filed a MedWatch report on August 14, 1998. However, it seems that the report taken from me by FDA investigator Joseph Despins was actually an investigative report which he subsequently filed with Dr. Tony Carreras of the Division of Scientific Investigations. My understanding is that the subsequent investigation was dropped after it was discovered that DMPS was nominated for the Bulk Drug List.

I have today, therefore, filed a MedWatch report regarding my experience with this drug. Because there was some discussion that the MedWatch reporting system is not equipped for handling reports of adverse events for unapproved drugs, I am sending a copy to you to ensure that it is officially recorded.

I hope that the FDA is reviewing the appropriateness of this drug for inclusion on the Bulk Drug List. If I can be of assistance in any way, please do not hesitate to contact me. Thank you for your time and attention to this important matter.

Sincerely,

98D-0272

C14

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Form Approved: OMB No. 0910-0291 Expires: 8/31/00
See OMB statement on reverse

FDA Use Only

Triage unit sequence #

Page ___ of ___

PLEASE TYPE OR USE BLACK INK

## A. Patient information

1. Patient Identifier: In confidence

2. Age at time of event: 49 or Date of birth:

3. Sex: ☑ female ☐ male

4. Weight: 135 lbs or ___ kgs

## B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death (mo/day/yr)
- ☑ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☑ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo/day/yr): 2-27-98

4. Date of this report (mo/day/yr): 7-17-00

5. Describe event or problem

Consulted physician for mild hypothyroidism. He injected me with 250 mg of DMPS (dimercapto propane sulfonate) as part of a "DMPS challenge" test to prove that mercury from my dental fillings was affecting my thyroid. From this injection, I suffered disabling fatigue, nausea, diarrhea, stomach pain, headaches, cognitive impairment, severe depression, suicidal ideation and psychotic episodes. It took over a year to become "normal" again, but I am still not back to the health I had prior to this injection.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Had been diagnosed with asymptomatic hypothyroidism and was taking .05mg synthroid.

## C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Dimercapto propane sulfonate 250mg.

#2

2. Dose, frequency & route used

#1 IM - 250mg

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 2-27-98

#2

4. Diagnosis for use (indication)

#1 hypothyroidism

#2

5. Event abated after use stopped or dose reduced

#1 ☐ yes ☑ no ☐ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1 ☐ yes ☐ no ☑ doesn't apply

#2 ☐ yes ☐ no ☑ doesn't apply

9. NDC # (for product problems only)

– –

10. Concomitant medical products and therapy dates (exclude treatment of event)

## D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date (mo/day/yr)

6.
- model #
- catalog #
- serial #
- lot #
- other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

## E. Reporter (see confidentiality section on back)

☐ yes ☑ no

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

☐ manufacturer
☐ user facility
☐ distributor

FDA

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.